REMARKS

Claims 1-141 are pending in the present application. Claims 1-8 15-18 and 141 have been amended herein. No new matter has been added. Upon entry of the present amendment, claims 1-8, 15-18, 140 and 141 will be pending. Applicants have amended all claims to be independent.

Since the amendments to the claims remove issues for appeal (*i.e.*, indefiniteness), Applicants respectfully request that they be entered into the record. See, M.P.E.P. § 714.12.

I. The Claims Are Clear And Definite

Claims 1-8, 15-18 and 140-141 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Applicants traverse the rejection and respectfully request reconsideration because the claims are clear and definite.

The Office Action asserts that claim 1, and claims depending therefrom, are indefinite because the claims do not recite whether modulation is upward or downward. Applicants reiterate that modulation can be either an increase or decrease. Indeed, Applicants teach at page 10, lines 12-13 of the specification that the term "modulates" means an increase or decrease. One skilled in the art would readily be able to determine whether a particular compound increased or decreased the activity of prokaryotic elongation factor p. Thus, the claims are definite within the meaning of § 112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Solely to advance prosecution of the present application, however, Applicants have amended claims 1, 3 and 6 to replace "modulates" with "increases or decreases" or forms thereof. As set forth above, the specification provides ample support for the phrase "increases or decreases." No new matter has been added. In addition, no change in claim scope is intended.

Claim 1 is also asserted to be indefinite due to the phrase "determining whether said compound modifies activity of efp," because there allegedly is no indication of how to carry out such a step since there are no measurement steps included in the method. Applicants respectfully point out that the description of the invention is the role of the specification, not the claims. *Orthokinetics, Inc.*

v. Safety Travel Chairs, Inc., 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986). In addition, the amount of detail required to be included in the claims is not to be viewed in the abstract but in conjunction with the specification. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 225 U.S.P.Q. 634 (Fed. Cir. 1985). As such, the specification contains numerous examples of determining whether a compound modifies activity of efp. For example, Applicants teach at page 15, lines 1-6 that whether a compound modifies the activity of efp can be determined by, for example, determining whether the compound can bind to efp. In addition, binding can be determined by, for example, numerous are-recognized procedures (see, page 15, lines 7-23 of the specification). No evidence has been presented in the Office Action that would suggest otherwise.

Activity, as used in the present application (see, page 8, lines 19-24 of the specification) refers to a variety of measurable indicia suggesting or revealing binding, either direct or indirect; affecting a response (*i.e.*, having a measurable affect in response to some exposure or stimulus, including, for example, the affinity of the compound for directly binding efp or a ribosome, or, for example, measurement of amounts of upstream or downstream proteins or other similar functions after some stimulus or event). Thus, determining whether a particular compound binds to efp is indicative of whether the compound increases or decreases the activity of efp.

Claim 1 is also alleged to be indefinite because "the compound to be identified is not named or described" (see, page 5 of the Office Action). One skilled in the art, however, need not know the name or description of a compound. Indeed, a never before described or known compound can be employed in Applicants' claimed inventions. For example, compound "X" which has been discovered in the Brazilian rain forest can be contacted with efp as recited in claim 1. One skilled in the art need not know the name of compound "X" or have any description of compound "X" to practice the claimed invention. Indeed, **any** compound can be used in the claimed inventions. Further, all that is required under the law is that one skilled in the art be able to determine whether something is a compound. Clearly, skilled artisans can determine whether something is a compound. No evidence has been presented in the Office Action that would suggest otherwise.

Claim 6 is purportedly indefinite in similar respect to claim 1. In particular, the Office Action alleges that the claim does not recite what activity of the efp is being modulated. Again, the

description of the invention is the role of the specification, not the claims. *Id.* The term "activity" is sufficiently described in the specification, as described above. Further, determining whether the compound that increases or decreases the activity of efp also increases or decreases the activity of other protein(s) essential for the functioning of efp can be determined, as described above, by determining whether the compound binds to the other protein. No evidence has been presented in the Office Action that would suggest otherwise.

The Office Action also asserts that "other protein(s)" are not described or named and further asserts that the limitations of the specification cannot be read into the claims. The claims, however, sufficiently define the invention such that one skilled in the art can determine what subject matter is or is not within the scope of the claims (*i.e.*, one skilled in the art can determine whether a particular protein is essential for the functioning of efp). That is, any protein that is essential for the functioning of efp is within the scope of the claim as it relates to the phrase "other protein(s)." Indeed, Applicants teach examples of such "other protein(s)" in the specification. A particular example is the L16 protein. In contrast to the suggestion in the Office Action, "L16" need not be recited in claim 6 to render claim 6 definite. Indeed, claim 6 is definite within the meaning of the patent laws in its present form. No evidence has been presented in the Office Action that would suggest otherwise.

In view of the foregoing, persons of ordinary skill would have no difficulty in determining whether a particular method meets the criteria recited in the claims. Accordingly, the claims are definite within the meaning of § 112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Thus, claims 1-8, 15-18 and 140-141 are clear and definite. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

II. The Claimed Invention Is Sufficiently Enabled

Claims 1-8, 15-18, 140 and 141 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to provide a disclosure that is enabling for the full scope of the claims. Applicants

traverse the rejection and respectfully request reconsideration because one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation.

As a preliminary matter, the Office Action's characterization of the claimed invention on page 2 is incorrect. In particular, the Office Action asserts that the claimed invention is directed, in part, to detection and/or characterization of "new compounds." In contrast, the claimed invention is not limited to only "new compounds." Rather, claim 1 is directed to identifying **any** compound that increases or decreases the activity of prokaryotic elongation factor p, as recited in claim 1. The term "new" nowhere appears in Applicants' claims. Further, an "old" compound may be identified in the presently claimed methods and, thus, may be classified as a "new" antibiotic.

As will be recognized, the enablement requirement of § 112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under § 112 is whether one skilled in the art would be able to practice the invention without undue experimentation). In this respect, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

> The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.
>
> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken as in compliance with the enabling requirements of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. (emphasis added)

Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so

expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974). No such evidence, however, has been provided to support this conclusion.

The Office Action, rather, concludes that one skilled in the art would be required to perform undue experimentation to practice the claimed inventions because Applicants have allegedly failed to provide the following: 1) how the compound is determined; 2) what the compound is; 3) what efp activity will be modulated; 4) what effect the modulation will have on the function of the efp; and 5) a specific assay and measurement steps to achieve all of the above. Applicants submit that none of the "factors" recited in the rejection in the Office Action point out the non-enablement of Applicants' claimed invention. To the extent that the factors are even relevant, they, in fact, point out the **enablement** of Applicants' claimed invention.

The factors identified as "how the compound is determined" and "what the compound is" are irrelevant to the analysis of enablement. Indeed, no compound is "determined" in Applicants' claimed invention. Rather, a compound that increases or decreases activity of efp is "identified" by performing the recited steps. Any compound can be selected and screened by the practitioner as desired. Further, as described above, one skilled in the art need not know what the compound is (e.g., name or description) to practice the claimed invention.

In regard to "what efp activity will be modulated," activity, as described above, is used in the present application (see, page 8, lines 19-24 of the specification) to refer to a variety of measurable indicia suggesting or revealing binding, either direct or indirect; affecting a response (*i.e.*, having a measurable affect in response to some exposure or stimulus, including, for example, the affinity of the compound for directly binding efp or a ribosome, or, for example, measurement of amounts of upstream or downstream proteins or other similar functions after some stimulus or event). Determining whether a particular compound binds to efp is indicative of whether the compound increases or decreases the activity of efp. Thus, Applicants provide ample guidance for practicing the claimed inventions.

The Office Action asserts that the methods or procedures include new *in vitro* methods as well as new *in vivo* methods. The Office Action further asserts that the specification provides "only examples and no specific assays" to accompany the claimed method. As set forth above, however,

the specification provides numerous art-recognized assays (see, page 15, lines 7-23 of the specification). In addition, one embodiment of Applicants' claimed invention (e.g., tryptophan fluorescence) is set forth in Example 2 of the specification. Thus, Applicants provide broad general teachings of assays, as well as particular working examples of carrying out the claimed invention.

The Office Action appears to suggest that Applicants must provide some indicia of how the claimed method is an improvement over the prior art. Applicants, however, are not required to provide any indicia of improvement. Applicants respectfully request that the Examiner point out authority for such an alleged requirement. The Office Action also asserts that it appears that the new method "encompasses a lot of old methods" and that Applicants are relying on art-recognized procedures for the "new" claimed methods. The assays employed in particular embodiments of the claimed invention, however, need not be new assays to render the claim inventions enabled. Clearly, if the Examiner is of the belief that "old assays" can be used to carry out the claimed invention, then the claims are clearly enabled. To the extent that it is even relevant in determining enablement, a "new" method, as used in the Office Action, can be "new" for a variety of reasons (e.g., new assays steps, new use, steps performed using a compound for which the steps have not been previously performed, etc.).

In regard to "what effect the modulation will have on the function of the efp," such information is not relevant to the enablement analysis. Indeed, one skilled in the art can identify a compound that increases or decreases the activity of efp without knowing what effect such an increase or decrease will have on efp. Indeed, Applicants are not required to recite the downstream effects of any particular compound on the activity of efp to enable the claimed invention. Applicants need only enable the claimed invention. In any event, Applicants teach at, for example, page 4, lines 7-13 of the specification, that the methods of the invention can be used, for example, to screen for antibiotics. Because elongation factor p is essential for bacterial cell viability, one potential effect of decreasing the activity of efp is to identify compounds that can decrease cell viability (e.g., anti-bacterial agent).

In regard to providing a "specific assay and measurement steps," as described above (in section I of the present response), Applicants provide ample guidance for determining whether a

compound increases or decreases the activity of efp. The Office Action admits that the claims broadly recite a method of identifying a compound that modulates the activity of efp (see, page 4 of the Office Action). Such broad teaching is clearly supported throughout the specification. In addition, the Office action erroneously asserts that Applicants fail to provide "specific assay and measurements." As stated above, however, Applicants teach numerous specific assays (including, but not limited to, binding assays such as, for example, gel-shift mobility electrophoresis, Western blot, filter binding, and scintillation proximity assays, and by measuring the intrinsic fluorescence of efp; see, page 15, lines 1-23 of the specification). Applicants also provide a working example of using tryptophan fluorescence to determine modulation of efp activity (see, Example 2).

In sum, one skilled in the art is able to practice Applicants' claimed invention without being required to perform undue experimentation. Indeed, the Office Action fails to identify any particular experimentation, let alone undue experimentation, that is required to carry out the claimed methods. The reasoning provided in the Office Action is merely conclusory statements wholly unsupported by any evidence. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

III. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (215) 564-8906 if there are any questions regarding Applicants' claimed invention. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully submitted,

Paul K Legaard

Paul K. Legaard
Registration No. **38,534**

Date: **August 29, 2001**

WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-8, 15-18 and 141 have been amended as follows:

1. (Amended) A method for identifying a compound [which modulates] that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound modifies activity of efp.

2. (Amended) [The method of claim 1 wherein step (b) comprises] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound binds to efp.

3. (Amended) [The method of claim 2 wherein step (b) is determined by] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound binds to efp by measuring the intrinsic fluorescence of efp and determining whether said intrinsic fluorescence is [modulated] increased or decreased by said binding.

4. (Amended) [The method of claim 3] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound binds to efp by measuring the intrinsic fluorescence of efp and determining whether said intrinsic fluorescence is increased or decreased by

said binding, wherein said intrinsic fluorescence of efp is measured as a function of the tryptophan residue(s) of efp.

5. (Amended) [The method of claim 4] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound binds to efp by measuring the intrinsic fluorescence of efp and determining whether said intrinsic fluorescence is increased or decreased by said binding, wherein said intrinsic fluorescence of efp is measured as a function of the tryptophan residue(s) of efp, wherein said fluorescence of efp is measured and compared to the fluorescence intensity of efp in the presence of the compound, wherein a decrease in fluorescence intensity indicates binding of efp.

6. (Amended twice) [The method of claim 1 further comprising step:] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound;

(b) determining whether said compound modifies activity of efp; and

(c) determining whether said compound which [modulates] increases or decreases the activity of efp [modifies] increases or decreases the activity of other protein(s) essential for the functioning of efp.

7. (Amended) [The method of claim 6] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound;

(b) determining whether said compound modifies activity of efp; and

(c) determining whether said compound that increases or decreases the activity of efp increases or decreases the activity of [wherein said other protein essential for the functioning of efp is] L16 protein.

8. (Amended) [The method of claim 2 wherein step (b) comprises] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound binds to efp by a binding assay selected from the group consisting of gel electrophoresis, Western blot, filter binding, and scintillation proximity assay.

15. (Amended twice) [The method of claim 1] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound modifies activity of efp, wherein efp is isolated from a natural source.

16. (Amended) [The method of claim 15 wherein said natural source is] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound modifies activity of efp, wherein efp is isolated from a prokaryotic organism.

17. (Amended) [The method of claim 16 wherein said prokaryotic organism is] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound modifies activity of efp, wherein efp is isolated from a bacteria.

18. (Amended) [The method of claim 17 wherein said bacteria is] A method for identifying a compound that increases or decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound modifies activity of efp, wherein efp is isolated from a bacteria selected from the group consisting of *E. coli*, *S. aureus*, *S. pneumoniae*, *H. influenzae*, and an *Enterococcus* species.

141. (Amended) [A method of claim 140] A method of modulating the activity of L16 protein comprising contacting said L16 protein in association with efp with an oxazolidinone compound, wherein said L16 protein in association with efp is in a cell or cell preparation.